

Center Number: ___ Participant Number: ___ _ Participant's Initials: ___ __

		first middle last
Ir	nformed Consent	
١,	Did participant present for baseline visit?	
-	\square_0 No \rightarrow If No: Specify reason (check only one): \square_1 Failed an eligibility criterion (participant no longer meets criteria)	
	Lost interest in the study	
	Will take too much time	
	\square_{4} Scheduling conflicts with work or school	
	5 Doesn't like the study's procedures	
	Unwilling to be randomized	
	Lives too far away/transportation problems	
	Needs help with child care (unanticipated child care needs)	
	Lagrange Refused with no explanation	
	Unable to contact	
	□₁ Yes	
2	Date and time study baseline informed consent signed:/:	
	ddy	



		Center Number:	Participant Number:	Participant's Initials: first middle last					
In	Informed Consent Detail								
Tiss	Tissue consent:								
			Check only one						
	Sample type	Participant consent given for future studies by Calerie and external investigators	Participant consent given for future studies by Calerie	Participant consent not given					
	1 Blood archive			\square_3					
	2 Urine archive			\square_3					
	3 Muscle biopsy archive			\square_3					
	4 Fat biopsy archive		\square_2	\square_3					



		Center Number: _	Participant Number:	Participant's Initials: middle last
C	linic Weight			
W	eight date and time:/ _{month}	/	:	Staff initials:
	R Not done → Specify reason (use Code			first middle last
Cli	nic weight (if the first two measurements a	re more than 0.1 kg	g apart, measure weight a third time):	
W	eight 1:	_ kg		
W	eight 2:	_ kg		
W	eight 3:	_ kg		
W	eight of gown:	_ kg		
	ital Signs			
As	sessment date and time:/	/	::	
	If waist measurement not done → Sp	ecify reason (use o	codelist below):	
1	Natural waist measurement (if the first two measurements are more than	1.0 cm apart, measu	ure natural waist circumference a third time):	Staff initials:
	Natural waist measurement 1:	·	cm	
	Natural waist measurement 2:	·	cm	
	Natural waist measurement 3:	·	cm	
2	Umbilical point waist measurement (if the umbilical point waist circumference a third time.		ments are more than 1.0 cm apart, measure	
	Umbilical point waist measurement 1	:	cm	
	Umbilical point waist measurement 2	:	cm	
	Umbilical point waist measurement 3	:·	cm	
3	Pulse: bpm OR Not dor	ne → Specify reas	son (use codelist below):	Staff initials:
4	Temperature:°C C	R Not done → S	pecify reason (use codelist below):	Staff initials:
5	Respirations: per minute OR	Not done → Spe	ecify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):1	eft arm \square_2 Rig	ht arm	Staff initials:
	6a Blood pressure 1:/	mm Hg	Time:: OR Not done - Specify rea	→ son (use codelist below):
	6b Blood pressure 2:/	mm Hg	Time:::	
	6c Blood pressure 3:/	mm Hg	Time:::	
No	ot Done Codelist: 1 Participant refused	2 Clinician unable	e to obtain 3 Insufficient time 4 Instr	ument failure 5 Not required



	Center Number: Parti	cipant Number: Po	articipant's Initials: First middle last
12-Lead ECG			
Date and Time		Findings	Staff Initials
/	Abnormal, not	clinically significant (specify): cally significant (specify):	first middle last
Safety Labs	'		
Date and time of last meal:	//	00:00 to 23:59	
Date and time of sample collection:	//	::	
Sample	Sample Complet	e? If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□₀ No □₁ Yes		first middle last
Urine	□ ₀ No □ ₁ Yes		first middle last
Not Done Codelist: 1 Participant refused 2	Clinician unable to obtain	3 Insufficient time 4 Instrument fa	ilure 5 Not required



Baseline Submission 1

Cen	ter Number: _	Par	icipant Number: Participant's Initials:				
Date completed:/ _{month} / _{year}	Date completed: /						
Abbreviated Medical History	/						
List any clinically significant changes occurring since Screening medical history was completed.							
Assessments Body System							
body System	No Change	Yes	If Yes, Specify Diagnosis				
1 Head, Ears, Eyes, Nose, Throat	\Box_{o}	□₁→					
2 Dermatologic	\Box_{o}	$\square_1 \rightarrow$					
3 Cardiovascular		□,→					
4 Respiratory		□,→					
5 Gastrointestinal		$\square_1 \rightarrow$					
6 Endocrine/Metabolic		$\square_1 \rightarrow$					
7 Genitourinary		$\square_1 \rightarrow$					
8 Neurological		$\square_1 \rightarrow$					
9 Blood/Lymphatic	\square_{o}	□₁→					
10 Musculoskeletal		□,→					
11 Hepatic		□₁→					
12 Drug Allergies	\square_{o}	□₁→					
13 Other Allergies		□₁→					
14 Psychological/Psychiatric		□₁→					
15 Other							
Physician's Signature							
Signature:			Date: / /				



Center Number: ___ __ Participant Number: ___ __ Participant's Initials: ___ __

Physical Examination							
Date of examination:/							
Dody Cyston		Assessments		If Ahmannal on Not Bonor Evaluin			
Body System	Normal	Abnormal	Not Done	If Abnormal or Not Done: Explain			
General appearance:		□₀→	₉₇ →				
2 Head, Ears, Eyes, Nose, Throat:		□₀→	₉₇ →				
3 Neck:		□₀→	₉₇ →				
4 Heart:		□₀→	₉₇ →				
5 Lungs:		□₀→	₉₇ →				
6 Abdomen:		□₀→	□ ₉₇ →				
7 Lymph nodes:		□₀→	₉₇ →				
8 Extremities/Skin:		□₀→	□ ₉₇ →				
9 Neurological:		□₀→	₉₇ →				
10 Musculoskeletal:		□₀→	₉₇ →				
	Normal	Abnormal	Not Done *				
11 Genitourinary:		□₀→	₉₇ →				
12 Breast:		□₀→					
Physician's Signature							
Investigator:	signati	ure		Date:/			

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4 Instrument failure

5 Not required

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time



Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain

Baseline Submission 1 Visit 2

	Center Number:	Participant Number:	Participant's Initials: _{first middle last}
Clinic Weight			
Weight date and time:	/	: 00 to 23:59	Staff initials:
	ason (use codelist below):		TITST mildale last
Clinic weight (if the two meas	urements are more than 0.1 kg apart	measure weight a third time):	
Weight 1:	kg		
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		
Pregnancy Test			
Complete only for femal	es.		
Does participant have r	eproductive potential?		
□ ₀ No			
Yes → If Yes: Date (rine pregnancy test performed:	/	
Result	s:1 Negative		

3 Insufficient time

4 Instrument failure

5 Not required



OR Not done → Specify reason (use codelist below): 2 DLW dose mixture ID and bottle number:	Participant's Initials: first middle last
OR Not done → Specify reason (use codelist below): 2 DLW dose mixture ID and bottle number:	
2 DLW dose mixture ID and bottle number:	Staff initials:
3 Exact weight of DLW mixture:	
Collection Sample Date and Time Co Pre dosing (PD) PDa ————————————————————————————————————	
Collection Sample Date and Time Co Pre dosing (PD) PDa —/	
Pre dosing (PD) PDa	
PDb —/	ollected
Day 0 (Visit 2) D0a/	00:00 to 23:59
	: 00:00 to 23:59
DOb/	:::::::
Day 7 (Visit 3) D7a	:
D7b —	::
Day 14 (Visit 4) D14a ———————————————————————————————————	:::
D14b —/	:::
5 Affix CRF page label(s) corresponding to this urine sample set: Affix Label Here	

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required



	Center Number:	Participant Number:	Participant's Initials:				
DXA Scan							
 Has the participant taken a calcium supplement today? □₀ No □₁ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center. Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? □₀ No □₁ Yes 							
DXA Scan		DXA Reso	an OR \square_{96} NA				
Date of scan:/		Date of rescan:/					
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	1	a Scanned all that apply				
☐ Whole body		☐ Whole	body				
Forearm		Forearn	ו				
Spine		Spine					
☐ Н ір		☐ Hip					
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	in 3 Insufficient time 4 Insti	rument failure 5 Not required				



		Center Number:	Participant I	Number:	Participant's Ir	nitials: first middle last
Da	ite completed:/ _{month} /	OR Not don	e → Specify re	ason (use codelist be	low):	
	rofile of Mood States	7				
In	structions: Please describe how you	feel right now by ch	necking one bo	x for each of the we	ords listed below.	
	Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1	Friendly				\square_3	4
2	Tense	\square_{o}		\square_{2}	\square_3	4
3	Angry					4
4	Worn out					
5	Unhappy					4
6	Clear-headed				$\square_{_3}$	4
7	Lively					4
8	Confused					
9	Sorry for things done					4
10	Shaky	\square_{o}			\square_3	4
11	Listless				\square_3	4
12	Peeved	\square_{o}				4
13	Considerate				\square_3	4
14	Sad	\square_{o}			\square_3	4
15	Active					4
16	On edge	\square_{o}			\square_3	4
17	Grouchy					4
18	Blue				\square_3	4
19	Energetic					4
20	Panicky				\square_3	
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No	ot Done Codelist: 1 Participant refused	2 Clinician unable to a	obtain 3 Insuff	ficient time 4 Instru	ment failure 5 N	ot required

Participant's Initials: first middle last



	Center Number: _	Participal	nf Number:	Participant's	first middle last
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless					4
22 Relaxed					
23 Unworthy					4
24 Spiteful			\square_{2}	\square_3	4
25 Sympathetic				\square_3	4
26 Uneasy			\square_{2}	\square_3	4
27 Restless				\square_3	4
28 Unable to concentrate			\square_{2}	\square_3	4
29 Fatigued				\square_3	4
30 Helpful			\square_{2}	\square_3	4
31 Annoyed				\square_3	4
32 Discouraged			\square_{2}		4
33 Resentful				\square_3	4
34 Nervous					4
35 Lonely				\square_3	4
36 Miserable					4
37 Muddled					4
38 Cheerful					4
39 Bitter					4
40 Exhausted				\square_3	
41 Anxious					4
42 Ready to fight	o			\square_3	4
43 Good-natured					4

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	Center Number: _	Participa	nt Number:	Participant's	Initials: first middle last
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy					4
45 Desperate					4
46 Sluggish	\square_{o}				4
47 Rebellious					4
48 Helpless					
49 Weary					4
50 Bewildered					
51 Alert					4
52 Deceived					
53 Furious					4
54 Efficient	\Box_{o}				
55 Trusting					4
56 Full of pep					
57 Bad-tempered					4
58 Worthless					
59 Forgetful					4
60 Carefree	\square_{o}		\square_{2}	\square_3	4
61 Terrified				\square_3	4
62 Guilty				\square_3	4
63 Vigorous	\square_{o}			\square_3	4
64 Uncertain about things	\square_{o}		\square_{2}	\square_3	
65 Bushed					4

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Center Number: Participant Nu	mber:		Participant [*]	's Initials:	first middle last
Date completed:/OR Not done → Specify reas	on (use code	list below):			
Perceived Stress Scale (PSS)					
Instructions: The questions in this scale ask you about your feelings and though indicate how often you felt or thought a certain way. Please check				-	lease
	Never	Almost Never	Some- times	Fairly Often	Very Often
1 In the last month, how often have you felt that you were unable to control the important things in your life?				\square_3	4
2 In the last month, how often have you felt confident about your ability to handle your personal problems?				\square_3	4
3 In the last month, how often have you felt that things were going your way?				\square_3	
4 In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?				\square_3	
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insuffici	ent time 4	Instrument	failure 5	Not requi	red



Center Number: Participa	nt Number:	Partic	cipant's Initials	first middle last
Date completed: $\underline{\hspace{1cm}}_{day}$ / $\underline{\hspace{1cm}}_{month}$ / $\underline{\hspace{1cm}}_{year}$ OR Not done \rightarrow Specify	reason (use code	list below):		
Pittsburgh Sleep Quality Index (PSQI)				
Instructions: The following questions relate to your usual sleep habits du the most accurate reply for the majority of days and nights				
During the past month	-		-	
1 When have you usually gone to bed?:				
2 How long (in minutes) has it taken you to fall asleep each	h night?	minu	tes	
3 When have you usually gotten up in the morning?	to 23:59			
4 How many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.) hours				
5 During the past month, how often have you had trouble sleeping because you (check only one answer per question)	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
a Cannot get to sleep within 30 minutes				\square_3
b Wake up in the middle of the night or early morning	\square_{o}			\square_3
c Have to get up to use the bathroom				\square_3
d Cannot breathe comfortably				\square_3
e Cough or snore loudly				\square_3
f Feel too cold				\square_3
g Feel too hot				\square_3
h Have bad dreams				\square_3
i Have pain				\square_3
i Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s):				\square_3
6 During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				\square_3
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Participant's Initials: first middle last



	Center Nun	nber: Participe	ant Number:	Part	first middle last	
Pi	ttsburgh Sleep Quality Index (P	SQI) (continued)				
			Never	Once or twice	Once or twice each week	3 or more times each week
7	During the past month, how often have y staying awake while driving, eating mea social activity?					\square_3
			No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8	During the past month, how much of a been for you to keep up enthusiasm to	•				3
			Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you quality overall?	ı rate your sleep	□ _o			

Participant's Initials: first middle last



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed: —/—	OR Not done → Specify	reason (use codelist below):		

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.

If you have any questions, please ask the person who gave you the inventory for help.

Section 1—Sexual Cognition/Fantasy										
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day	
1.1 A sexually attractive person	□ _o				4	5			8	
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)					4	5	6		8	
1.3 Erotic or romantic situations					4	5	6		8	
1.4 Caressing, touching, undressing, or foreplay					4	5	6		8	
1.5 Sexual intercourse, oral sex, touching to orgasm					4		6	7	8	
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Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required										

Participant's Initials:

first middle last



Center No.	ımber:	Po	articipant N	umber: _		Par	ticipant's	Initials:	rst middle last
Derogatis Interview for Sexual	Functi	on (DIS	F-SR) (F)	Female \	/ersion (continued)		
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone				3	4		6	7	8
2.2 Actively seek sexual satisfaction					4	5			8
2.3 Feel sexually aroused with a partner				3			6		8
	Never	Rarely	Sometimes	Usually	Always			•	
2.4 Have normal lubrication with masturbation					4				
2.5 Have normal lubrication									

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throughout sexual relations



Center I	Number:	Po	articipant N	lumber: _		Po	ırticipant's	Initials: ${f}$	rst middle last
Derogatis Interview for Sexua	Functi	on (DIS	SF-SR) (F)	Female \	/ersion (d	ontinue	d)		
Section 3—Sexual Behavior/Experience	es								
During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories				\square_3	4	5			8
3.2 Masturbation				3	□ ₄	5			□ ₈
3.3 Casual kissing and petting						5			8
3.4 Sexual foreplay						5			8
3.5 Sexual intercourse, oral sex, etc.				\square_3	4	5			
Section 4—Orgasm									
During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at	Slightly	Moderately	Highly	Extremely				
4.1 Your ability to have an orgasm				\square_3	4				
4.2 The intensity of your orgasm	o			3	4				
4.3 The ability to have multiple orgasms (if typical for you)				\square_3	4				
4.4 Feelings of closeness and togetherness with your partner	o			\square_3	4				
4.5 Your sense of control (timing) of your orgasm					4				
4.6 Feeling a sense of relaxation and well-being after orgasm				3					

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Participant's Initials: first middle last



Baseline Submission 1

	Center Number:		Participant	Number:		F	'articipant'	s Initials:	first middle last	
Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)										
Section 5—Drive and Relationship										
	Not at all	Less than 1	1 or 2 per	1 per week		4 to 6 per	1 per day	2 or 3 per	4 or more	

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?						5		7	
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?				\square_3	4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				\square_3	4				
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?				3	4	5	6		8

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Participant's Initials: first middle last

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Baseline Submission 1

C. I. M.						ъ	, .		SIT Z
Center No.	umber:	Partici	pant Num	ber:		Parti	cipant's Ir	firs	t middle last
Date completed:/OR Not on the complete of the com	done → Spec	ify reaso	on (use co	delist be	low):				
Derogatis Interview for Sexual	Function	(DISF-S	R) (M) N	Nale Ver	sion				
Instruction: Below you will find a brief set of quest sections that ask about different aspects of your sex while another inquires about the kinds of sexual esexual arousal and the quality of your orgasm. relationship.	cual experient experiences	that you	section of have. You	asks abo ou are a	out sexu Iso aske	al fante d about t	isies or the natu	daydre re of you	ams, ur
On some questions you are asked to respond in activities asked about in that section. Some frequen frequency scales range from "0 = never" to "4 = also of a satisfaction scale. This type of scale tells how m Some satisfaction scales range from "0 = could not "0 = not at all satisfied," to "4 = extremely satisfied.	cy scales go f ways." In the nuch you enjo be worse" to	from "O case of yed, or v	= not at other qu were sati	all" to " estions, sfied by	8 = four you will the sexu	or more be asked al activit	times a I to resp y being	day." Of ond in to asked a	ther erms bout.
In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to ollow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best lescribes your personal experience.									
If you have any questions, please ask the person who gave you the inventory for help.									
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about	all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person					4	5			8
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)				\square_3	4	₅			8
1.3 Erotic or romantic situations					4	5			8
1.4 Caressing, touching, undressing, or foreplay				\square_3	4	5	6		8
1.5 Sexual intercourse, oral sex, touching to orgasm	g				4	5	□ ₆		8

Participant's Initials: first middle last

5 Not required

4 Instrument failure

2 Clinician unable to obtain

3 Insufficient time



Center Num	nber:	Par	ticipant Nu	mber:		Part	icipant's I	nitials:	st middle last
Derogatis Interview for Sexual F	unctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 A full erection upon awakening					4	5	6		8
2.2 A full erection during a sexual fantasy or daydream					4		6		
2.3 A full erection while looking at a sexually arousing person, movie, or picture					4				8
2.4 A full erection during masturbation							6		
2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay							6		

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through intercourse and orgasm

Participant's Initials: first middle last



Center Num	ber:	Pai	ticipant Nu	mber:		Pa	rticipant's	Initials:	st middle last	
Derogatis Interview for Sexual F	unctio	n (DISI	-SR) (M)	Male Ve	rsion (co	ntinued)				
Section 3—Sexual Behavior/Experiences										
During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day	
3.1 Reading or viewing romantic or erotic books or stories	o			\square_3	4	5				
3.2 Masturbation				\square_3	4	5	6		8	
3.3 Casual kissing and petting	o			\square_3	4	5	6		8	
3.4 Sexual foreplay	o			\square_3	4	5	6		8	
3.5 Sexual intercourse, oral sex, etc.					4	5			8	
Section 4—Orgasm										
During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely					
4.1 Your ability to have an orgasm					4					
4.2 The intensity of your orgasm	o			\square_3	4					
4.3 The length or duration of your orgasm	o			\square_3	4					
4.4 The amount of seminal liquid that you ejaculate	o			\square_3	4					
4.5 Your sense of control (timing) of your orgasm	o			\square_3	4					
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_3	_4					

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Participant's Initials: first middle last



Center	ter Number: Participant Number:					Participant's Initials: initials: initials				
Derogatis Interview for Sexua	ıl Fund	tion (DISF-SR) (M) Male \	Version (continue	4)			
Section 5—Drive and Relationship										
	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day	
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?						5	□ ₆	7	□ ₈	
	Not at all	Slightly	Moderately	Highly	Extremely					
5.2 During this period, how interested have you been in sex?					□ ₄					
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				\square_3	4					
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better	
5.4 In general, what would represent the best description of the quality of your sexual functioning?					4	5	□ ₆		8	

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Center Number: Po	articipant Nun	nber:		Participant's Initials:			
Date completed: $_{day}$ / $_{month}$ / $_{year}$ OR Not done \rightarrow S	pecify reasc	on (use cod	elist below)	:	_		
Food Cravings Questionnaire—Trait							
Please indicate the extent to which you agree with each statement be	low, in gen	eral, by ch	ecking the	appropr	iate box.		
	Never OR NA	Rarely	Some- times	Often	Usually	Always	
Being with someone who is eating often makes me hungry.					5		
2 When I crave something, I know I won't be able to stop eating once I start.					5	6	
3 If I eat what I am craving, I often lose control and eat too much.				4	5		
4 I hate it when I give in to cravings.					5	6	
5 Food cravings invariably make me think of ways to get what I want to eat.				4	5		
6 I feel like I have food on my mind all the time.			\square_3	4	5	6	
7 I often feel guilty for craving certain foods.				4	5		
8 I find myself preoccupied with food.				4	5	6	
9 I eat to feel better.				4	5		
10 Sometimes, eating makes things seem just perfect.				4	5	6	
11 Thinking about my favorite foods makes my mouth water.				4	5		
12 I crave foods when my stomach is empty.				4	5	6	
13 I feel as if my body asks for certain foods.				4	5	6	
14 I get so hungry that my stomach seems like a bottomless pit.					5	6	
15 Eating what I crave makes me feel better.				4	5	6	
16 When I satisfy a craving, I feel less depressed.					5	6	
17 When I eat what I am craving, I feel guilty about myself.				4	5		
18 Whenever I have cravings, I find myself making plans to eat.					5		
19 Eating calms me down.					5	6	
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain	3 Insufficie	ent time	1 Instrument	failure	5 Not requ	ired	

Participant's Initials: first middle last



Center Number: Parti	cipant Numb	oer:		Participan	t's Initials:	first middle last
Food Cravings Questionnaire—Trait (continued)						
	Never OR NA	Rarely	Some- times	Often	Usually	Always
20 I crave foods when I am bored, angry, or sad.					5	6
21 I feel less anxious after I eat.				4	5	6
22 If I get what I am craving, I cannot stop myself from eating it.						6
23 When I crave certain foods, I usually try to eat them as soon as I can.					5	6
24 When I eat what I crave, I feel great.					5	
25 I have no will power to resist my food crave.					5	6
26 Once I start eating, I have trouble stopping.			\square_3		5	
27 I can't stop thinking about eating, no matter how hard I try.				4	5	6
28 I spend a lot of time thinking about whatever it is I will eat next.					5	6
29 If I give in to a food craving, all control is lost.				4	5	6
30 When I'm stressed out, I crave food.					5	6
31 I daydream about food.					5	6
32 Whenever I have a food craving, I keep on thinking about eating until I actually eat the food.					5	6
33 If I am craving something, thoughts of eating it consume me.					5	6
34 My emotions often make me want to eat.			\square_3		5	6
35 Whenever I go to a buffet, I end up eating more than what I needed.						6
36 It is hard for me to resist the temptation to eat appetizing foods that are in my reach.					5	
37 When I am with someone who is overeating, I usually overeat too.					5	
38 When I eat food, I feel comforted.						
39 I crave foods when I'm upset.					5	6

Participant's Initials:

first middle last



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/	OR Not done →	Specify reason (use codelist below):		

Food Cravings Questionnaire—State (FCQ-S)

Below is a list of comments made by people about their eating habits. Please check one answer for each comment that indicates how much you agree with the comment right now, at this very moment. Notice that some questions refer to foods in general while others refer to one or more specific foods. Please respond to each item as honestly as possible.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I have an intense desire to eat [one or more specific foods].			\square_3	4	5
2	I'm craving [one or more specific foods].			\square_3	\square_{4}	5
3	I have an urge for [one or more specific foods]			\square_3	4	5
4	Eating [one or more specific foods] would make things seem just perfect.			\square_3		
5	If I were to eat what I am craving, I am sure my mood would improve.			\square_3	4	
6	Eating [one or more specific foods] would feel wonderful.		\square_{2}	\square_3	\square_{4}	
7	If I ate something, I wouldn't feel so sluggish and lethargic.			\square_3	4	5
8	Satisfying my craving would make me feel less grouchy and irritable.			\square_3		5
9	I would feel more alert if I could satisfy my craving.			\square_3	4	5
10	If I had [one or more specific foods], I could not stop eating it.			\square_3		5
11	My desire to eat [one or more specific foods] seems overpowering.			\square_3		5
12	I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			\square_3	4	5
13	I am hungry.			\square_3	4	5
14	If I ate right now, my stomach wouldn't feel as empty.			\square_3	4	5
15	I feel weak because of not eating.			\square_3	4	5

Participant's Initials:



Center Numb	er: Pa	rticipant Number:		Participant's	Initials: first middle last
Date completed:/OR	Not done → Sp	ecify reason (us	se codelist below	·):	
Food Craving Inventory (FCI-II)					
For each of the foods listed below, please check the ap	propriate box.				
Note: A craving is defined as an intense desire to cons	ume a particula		ype that is diff	icult to resist.	
Over the past month, how often have you experienced a craving for	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake			3	4	
2 Pizza			\square_3	4	
3 Fried chicken			3	4	
4 Gravy				4	
5 Sandwich bread			\square_3	4	
6 Sausage			\square_3	4	
7 French fries				4	
8 Cinnamon rolls				4	
9 Rice				4	
10 Hot dog				4	
11 Hamburger				4	
12 Biscuits				4	
13 Ice cream			\square_3	4	
14 Pasta				4	
15 Fried fish				4	
16 Cookies			\square_3	4	
17 Chocolate			\square_3	4	
18 Pancakes or waffles			\square_{3}	4	5
19 Corn bread			\square_3	4	
20 Chips			\square_3	\square_4	\square_5
21 Rolls			\square_3	4	
22 Cereal			\square_3	4	
23 Donuts			3	4	
24 Candy			3	4	
25 Brownies				4	
26 Bacon			\square_3	4	
27 Steak			\square_3		
28 Baked potato			\square_3		
Not Done Codelist: 1 Participant refused 2 Clinician un	nable to obtain	3 Insufficient tim	ne 4 Instrumer	nt failure 5 N	Not required
	N D	0211 T		Participant's	Initials:



		Center Number:	Participant Number:		Participant's I	nitials:
Date c	completed:/ _{month} /	OR Not done ¬	Specify reason (use code	list below):		
Eati	ng Inventory					
1	When I smell a sizzling ste difficult to keep from eatin	eak or see a juicy pie g, even if I have just	ece of meat, I find it v finished a meal.	very	☐₁ True	o False
2	I usually eat too much at s	ocial occasions, like	parties and picnics.		1 True	o False
3	I am usually so hungry the	at I eat more than th	ree times a day.		1 True	₀ False
4	When I have eaten my que not eating anymore.	ota of calories, I am	usually good about		, True	o False
5	Dieting is so hard for me b	pecause I just get too	hungry.		, True	☐₀ False
6	I deliberately take small h	elpings as a means	of controlling my we	ight.		o False
7	Sometimes things just taste I am no longer hungry.	e so good that I keep	o on eating even wh	en	₁ True	o False
8	Since I am often hungry, I expert would tell me that I something more to eat.			an	1 True	o False
9	When I feel anxious, I find	l myself eating.			1 True	□₀ False
10	Life is too short to worry o	about dieting.			, True	o False
11	Since my weight goes up o more than once.	and down, I have go	ne on reducing diets	S	, True	□₀ False
12	I often feel so hungry that	I just have to eat so	mething.			o False
13	When I am with someone	who is overeating, I	usually overeat too	•	₁ True	o False
14	I have a pretty good idea	of the number of ca	lories in common foo	od.	1 True	₀ False
15	Sometimes when I start ea	ating, I just can't seei	m to stop.			□₀ False
16	It is not difficult for me to l	eave something on	my plate.			o False
17	At certain times of the day to eating then.	, I get hungry becau	use I have gotten use	ed	☐₁ True	□₀ False
18	While on a diet, if I eat foo for a period of time to mal		·	ess	1 True	o False
Not D	one Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient time 4	Instrument	failure 5 N	lot required



Baseline Submission 1

		Center Number:	Participant Number:	Participant's Ir	first middle last
Eat	ing Inventory (continued)				
19	Being with someone who is	eating often makes	me hungry to eat also.	1 True	o False
20	When I feel blue, I often ove	reat.			o False
21	I enjoy eating too much to sp my weight.	poil it by counting o	calories or watching	, True	□₀ False
22	When I see a real delicacy, I right away.	often get so hungi	ry that I have to eat	, True	o False
23	I often stop eating when I ar limiting the amount I eat.	m not really full as	a conscious means of	, True	o False
24	I get so hungry that my stom	nach often seems li	ke a bottomless pit.		o False
25	My weight has hardly chang	ged at all in the last	ten years.		o False
26	I am always hungry so it is he food on my plate.	nard for me to stop	eating before I finish		o False
27	When I feel lonely, I console	myself by eating.		, True	o False
28	I consciously hold back at m	eals in order not to	gain weight.	, True	o False
29	I sometimes get very hungry	late in the evening	g or at night.	, True	□₀ False
30	I eat anything I want, any tir	me I want.		, True	☐₀ False
31	Without even thinking about	it, I take a long tin	ne to eat.	, True	o False
32	I count calories as a consciou	us means of contro	lling my weight.		□₀ False
33	I do not eat some foods become	ause they make me	e fat.	, True	□₀ False
34	I am always hungry enough	to eat at any time.		, True	□₀ False
35	I pay a great deal of attention	on to changes in m	y figure.	, True	□₀ False
36	While on a diet, if I eat a foo eat other high calorie foods.		ed, I often splurge and	, True	o False

calerie Phase 2

Baseline Submission 1 Visit 2

	Center Number:	Participant Number:	Participant's Initials:				
Eat	ing Inventory (continued)						
Plea	se check one answer that is most appropriate to you	for each question below.					
37	How often are you dieting in a conscious effort to control your weight?	☐₁ Rarely ☐₂ Sometimes	□₃ Usually □₄ Always				
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	\square_1 Rarely \square_2 Sometimes	□ ₃ Usually □ ₄ Always				
39	How often do you feel hungry?	Rarely Sometimes	□₃ Usually □₄ Always				
40	Do your feelings of guilt about overeating help you to control your food intake?	☐₁ Rarely ☐₂ Sometimes	□₃ Usually □₄ Always				
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐₁ Easy ☐₃ Moderately difficult	☐₂ Slightly difficult ☐₄ Very difficult				
42	How conscious are you of what you are eating?	□₁ Not at all□₃ Moderately	□₂ Slightly □₄ Extremely				
43	How frequently do you avoid "stocking up" on tempting foods?	☐₁ Almost never ☐₃ Usually	Seldom Almost always				
44	How likely are you to shop for low calorie foods?	☐₁ Unlikely ☐₃ Moderately likely	□₂ Slightly likely □₄ Very likely				
45	Do you eat sensibly in front of others and splurge alone?	☐₁ Never ☐₂ Rarely	□₃ Often □₄ Always				
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐₁ Unlikely☐₃ Moderately likely	□₂ Slightly likely □₄ Very likely				
47	How frequently do you skip dessert because you are no longer hungry?	☐₁ Almost never ☐₃ At least once a week	□₂ Seldom □₄ Almost every day				
48	How likely are you to consciously eat less than you want?	☐₁ Unlikely ☐₃ Moderately likely	☐₂ Slightly likely ☐₄ Very likely				
49	Do you go on eating binges though you are not hungry?	☐₁ Never ☐₃ Sometimes	☐₂ Rarely ☐₄ At least once a week				
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	Not like me Little like me Spretty good description of me Describes me perfectly					
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	□₀ Eat whatever you want, v □₁ Usually eat whatever you □₂ Often eat whatever you w □₃ Often limit food intake, b □₄ Usually limit food intake, □₅ Constantly limiting food in	want, whenever you want it vant, whenever you want it ut often "give in" rarely "give in"				



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/	OR Not done →	Specify reason (use codelist below):		

Weight Efficacy Lifestyle Questionnaire (WEL)

This form describes some typical eating situations. Everyone has situations which make it very hard for them to keep their weight down. The following are a number of situations relating to eating patterns and attitudes. This form will help you to identify the eating situations which you find the hardest to manage.

Read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to **successfully resist** the desire to eat. Check this number for each item.

I am confident that:		Not confident at all that you can resist the desire to eat						Very confident that you can resist the desire to eat					
		0	1	2	3	4	5	6	7	8	9		
1	I can resist eating when I am anxious (nervous).					4				8	9		
2	I can control my eating on the weekends.				\square_3	4	5	6		8	9		
3	I can resist eating even when I have to say "no" to others.					4	5						
4	I can resist eating when I feel physically run down.				\square_3			6		8	9		
5	I can resist eating when I am watching TV.					4				8			
6	I can resist eating when I am depressed (or down).				\square_3	4	5			8	9		
7	I can resist eating when there are many different kinds of food available.					4	5			8	9		
8	I can resist eating even when I feel it is impolite to refuse a second helping.				\square_3	4				8	9		
9	I can resist eating even when I have a headache.					4				8	9		
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required								d					

Participant's Initials:

first middle last



	Center Number: _	Participant Number:				Participant's Initials:							
Weight Efficacy Lifestyle Q	uestionna	ire (w	/EL) (cc	ontinue	d)								
I am confident that:			Not confident at all that you can resist the desire to eat					Very confident that you can resist the desire to eat					
		0	1	2	3	4	5	6	7	8	9		
10 I can resist eating when I am re	eading.						5	6		8	9		
11 can resist eating when I am of (or irritable).	angry							6		8	9		
12 I can resist eating even when I a party.	am at				\square_3	4	5	6		8	9		
13 I can resist eating even when a pressuring me to eat.	others are				\square_3			6		8	9		
14 I can resist eating when I am in	n pain.				$\square_{_3}$			6		8	9		
15 I can resist eating just before g bed.	oing to							6		8	9		
16 I can resist eating when I have experienced failure.						4		6		8	9		
17 I can resist eating when high-coare available.	alorie foods					4		6		8	9		
18 I can resist eating even when I others will be upset if I don't e								6		8	9		
19 I can resist eating when I feel uncomfortable.						4	5			8	9		
20 I can resist eating when I am h	арру.				\square_3			6					



		Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	t middle last
Da	te completed:/ _{month} /	OR Not done =	→ Specify	reason	(use code	elist belov	v):			
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)										
Ins	structions: Using the scale shown, ple	ase rate the following items	on a sca	le from 1						
				Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1	Fasting is a good way to los	e weight.				\square_3	4	5	6	
2	My sleep isn't as good as it	used to be.				\square_3	4	5	6	
3	I avoid eating for as long as	I can.				\square_3	4	5	6	
4	Certain foods are "forbidden	n" for me to eat.				\square_3	4	5	6	
5	I can't keep certain foods in m binge on them.	y house because I will				\square_3	4	5	6	
6	I can easily make myself vor	nit.					4	5	6	
7	I can feel that being fat is te	rible.				\square_3	4	5	6	
8	I avoid greasy foods.					\square_3		5	6	
9	It's okay to binge and purge	once in a while.					4	5		
10	I don't eat certain foods.						4	5		
11	I think I am a good person.						4	5		
12	My eating is normal.						4	5		
13	I can't seem to concentrate l	ately.					4	5	6	
14	I try to diet by fasting.					\square_3	4	5		
15	I vomit to control my weight.							5		
16	Lately nothing seems enjoya	ble anymore.								
17	Laxatives help keep you slim	ı .					4	5	6	
18	I don't eat red meat.							5		
19	I eat so rapidly I can't even	taste my food.						5	6	
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to obta	in 3 In	sufficient	time 4	Instrume	nt failure	5 No	t require	ed



	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials:	irst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	oms (MAEDS)				
	-	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid	being overweight.							
21 When I feel bloated, I must do s of that feeling.	omething to rid myse	elf			4	5	6	
22 I overeat too frequently.						5		
23 It's okay to be overweight.				\square_3		5		
24 Recently I have felt that I am o	worthless person.			\square_3	4	5	6	
25 I would be very upset if I gain	ed 2 pounds.			\square_3	4	5	6	
26 I crave sweets and carbohydro	ates.			\square_3	4	5	6	
27 I lose control when I eat.				\square_3		5	6	
28 Being fat would be terrible.				\square_3	4	5		
29 I have thought seriously about	t suicide lately.			\square_3	4	5	6	7
30 I don't have any energy anymo	re.			\square_3	4	5	6	
31 I eat small portions to control	my weight.			\square_3		5	6	
32 I eat 3 meals a day.				\square_3		5		
33 Lately I have been easily irrita	ited.			\square_3	4	5		
34 Some foods should be totally	avoided.			\square_3		5		
35 I use laxatives to control my w	veight.			\square_3		5	6	
36 I am terrified by the thought o	of being overweight.			\square_3	4	5		
37 Purging is a good way to lose	weight.			\square_3		5		
38 I avoid fatty foods.								



	Center Number:	Participant No	umber: _		Pai	rticipant's	nitials:	irst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue	e.			\square_3	4	5		
40 I am obsessed with becoming	overweight.			\square_3	\square_{4}	5	6	
41 I don't eat fried foods.				\square_3	4	5		
42 I skip meals.				\square_3	\square_4	5	6	
43 Fat people are unhappy.				\square_3	4	5		
44 People are too concerned wit	h the way I eat.			\square_3	\square_4	5		
45 I feel good when I skip meals	•			\square_3	4	5		
46 I avoid foods with sugar.				\square_3	\square_4	5	6	
47 I hate it when I feel fat.				\square_3	4	5		
48 I am too fat.				\square_3	\square_4	5	6	
49 I eat until I am completely stu	ffed.			\square_3	4	5		
50 I hate to eat.				\square_3	4	5	6	
51 I feel guilty about a lot of thin	gs these days.			\square_3	4	5		
52 I'm very careful of what I eat				\square_3	\square_4	5		
53 I can "hold off" and not eat e	ven if I am hungry.			\square_3	4	5		
54 I eat even when I am not hun	gry.			\square_3		5		
55 Fat people are disgusting.				\square_3	4	5		
56 I wouldn't mind gaining a few	v pounds.			\square_3	4	5	6	

Participant's Initials: first middle last



Center Number: Participant Number: Participant's Initials:								
Date completed:/ OR Not done → Specify reason (use codelist below):								
Body Shape Questionnaire (BSQ)								
We would like to know how you have been feeling about your appearance over the past four weeks . Please read each question and check the box for the appropriate choice. Please answer all the questions.								
Over the Past Four Weeks	Rarely	Some- times	Often	Very Often	Always			
1 Has feeling bored made you brood about your shape?			\square_3	4	5			
2 Have you been so worried about your shape that you have been feeling that you ought to diet?				4	5	6		
3 Have you thought that your thighs, hips, or bottom are too large for the rest of you?				4	5			
4 Have you been afraid that you might become fat (or fatter)?				4	5			
5 Have you worried about your flesh not being firm enough?					5			
6 Has feeling full (e.g., after eating a large meal) made you feel fat?				4	5	6		
7 Have you felt so bad about your shape that you have cried?			\square_3		5	6		
8 Have you avoided running because your flesh might wobble?			\square_3	4	5	6		
9 Has being with thin women/men made you feel self-conscious about your shape?			\square_3		5	6		
10 Have you worried about your thighs spreading out when sitting down?			\square_3		5	6		
11 Has eating even a small amount of food made you feel fat?			\square_3		5	6		
12 Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?			\square_3	4	5	6		
13 Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?				4	5			
14 Has being naked, such as when taking a bath, made you feel fat?			\square_3	4	5	6		
15 Have you avoided wearing clothes which make you particularly aware of the shape of your body?			\square_3		5	6		
16 Have you imagined cutting off fleshy areas of your body?			\square_3		5	6		
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Inst	fficient time	4 Instru	ıment failu	ıre 5 N	lot require	ed		



	Center Number:	Participant N	lumber: _		Par	ticipant's	Initials:	rst middle last
Body Shape Q	uestionnaire (BSQ) (continued)							
Over the Past Four W	eeks		Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating swee	ets, cakes or other high calorie fo	ood made				4		
	one out on social occasions (e.g., p eve felt bad about your shape?	parties)			\square_3		5	
19 Have you felt ex	xcessively large and rounded?				\square_3	4	5	
20 Have you felt a	shamed of your body?				\square_3	4	5	6
21 Has worry abou	ut your shape made you diet?				\square_3	4	5	
22 Have you felt he stomach has be	appiest about your shape when y en empty?	our/			\square_3		5	
23 Have you though	ght that you are the shape you ar ck self-control?	e			\square_3	4	5	6
	ed about other people seeing rol ur waist or stomach?	ls of			\square_3	4	5	6
25 Have you felt the thinner than you	nat it is not fair that other women, u?	/men are				4		
26 Have you vomit	ed in order to feel thinner?				\square_3	\square_{4}	5	
	iny, have you worried about taking sitting on a sofa or bus seat)?	ng up too			\square_3	4	5	
28 Have you worri	ed about your flesh being dimply	/?			\square_3	\square_{4}	5	
	r reflection (e.g., in a mirror or shop windo	ow) made				4	5	6
30 Have you pinch fat is there?	ed areas of your body to see ho	w much			\square_{3}		5	
	led situations where people could communal changing rooms or swimming pools,				\square_3	4	5	6
32 Have you taken	laxatives in order to feel thinner	?					5	
	particularly self-conscious about the company of other people?	your				4	5	6
34 Has worry about to exercise?	ut your shape made you feel you	ought			\square_3	4	5	6



Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain

Baseline Submission 1 Visit 3

	Center Number: _	Participant Number:	Participant's Initials:	
Clinic Weight			· first	t middle last
Weight date and time:/		: 00:00 to 23:59	Staff initials:	ıst
OR Not done → Specify reason (a Clinic weight (if the two measurement)		art, measure weight a third time):		
Weight 1:	kg			
Weight 2:	kg			
Weight 3:	kg			
Weight of gown:	kg			

3 Insufficient time

4 Instrument failure

5 Not required

Participant's Initials: first middle last

Participant Number:

Center Number:

Phase 2	
erie	
cal	

Se	ven-L	Seven-Day Physical Activity Recall (PAR)	ity Reca	II (PAR)											
Tod	Today's date: _	· · · · · · · · · · · · · · · · · · ·		Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below):	Mon Tue	ss Wed	Thurs	Fri S	at Su	ORNo	† done ↑	Specify re	eason (use	codelist bela	.w/):
_	Were yo	oyed in the last sev	n days?		Z Z	$_{0}$ No $ ightharpoonup$ Skip to question 3	stion 3	Tes				Interv	Interviewer initials:		first middle last
2	If Yes: W	If Yes: Which days (check all that apply)?	•		Mon	Tues Wed Thurs Fri	Wed	Thurs	ш	Sat	Sun				
m	Which d	Which days do you consider your weekend, or non-work, days?	reekend, or n	on-work, daysî	Mon	Tues	Med	Thurs	Œ.	Sat	Sun		l		
Dav	Day of		Sleek	Sleep Time	Work	Work Time	Mor	Morning (in minutes)	nutes)	Affer	Afternoon (in minutes)	ninutes)	Even	Evening (in minutes)	utes)
*	Week	Date	ln Bed	ηυ	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
▼ yester- day)		day /		00:00 to 23:59	00:00 to 23:59										
9		day //			00:00 to 23:59	00:00 to 23:59									
Ŋ					00:00 to 23:59	00:00 to 23:59									
4		day / month / veor		00:00 to 23:59 00:00 to 23:59	00:00 to 23:59										
9			00:00 to 23:59 00:00 to 23:59		00:00 to 23:59	00:00 to 23:59									
7		day /	00:00 to 23:59	00:00 to 23:59 00:00 to 23:59											
T week ago)		day / month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									

2 Clinician unable to obtain Not Done Codelist: 1 Participant refused

3 Insufficient time

4 Instrument failure

5 Not required



	Center Number: Participant Number: Participant's Initials:	first middle last							
S	even-Day Physical Activity Recall (PAR) (continued)								
4	Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)? More Less About the same								
In	Interviewer: Please answer questions below and note any comments on interview.								
5	Were there any problems with the Seven-Day PAR interview? No Yes								
6	Do you think this was a valid Seven-Day PAR interview? No Yes								
7	Were there any activities reported by the participant that you don't know how to classify?								



	ay Food Record plete below OR Not done → Spe	siby roason (uso Codeliet b	a dovele	cff	nitials.				
Com	piere below Ok Nor done Sper	ciry reason (use Codelist is	Staff initials: First middle last Replacement Values						
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)				
1	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	8	/	n Reliable up Unreliable up Missing				
2	/	1 Reliable 2 Unreliable 3 Missing	9	/	n Reliable up Unreliable up Missing				
3	/	1 Reliable 2 Unreliable 3 Missing	10	/	n Reliable unreliable shifts Missing				
4		☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	n Reliable number to the large state of the large s				
5	/	Reliable Unreliable Missing	12	/	n Reliable number to the limit of the limit				
6	/	Reliable Unreliable Missing	13	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing				



Concomitant Medications Log

	Center Number:	Participant Number:	Participant's Initials: first middle last
Concomitant Medica	itions Log		
	itions. Update form for each vis ch submission starting with base	ling over-the-counter and prescrip it and mark corresponding additional eline:	onal box.
Medication	Start Date or 🗸 if Pre-study	Stop Date or 🗹 if Continuing	Indication
Study vitamin-mineral supplement	day month year	day month year	
2 Study calcium supplement	/	//day month year	
3	OR 1 Pre-study	or	
4	OR 1 Pre-study	or1 Continuing	
5	OR 1 Pre-study	or1 Continuing	
6	OR 1 Pre-study	or1 Continuing	
7	OR 1 Pre-study	OR	
8	or	or	
9	OR 1 Pre-study	or	
10	OR 1 Pre-study	or1 Continuing	
11	OR 1 Pre-study	or1 Continuing	
12	day month year OR 1 Pre-study	day month year OR1 Continuing	



Concomitant Medications Log

	Center Number: Participant Number:	Participant's Initials: first middle last
Study Calcium Supplement	1000 mg	
Medication	Start Date	Stop Date
Study calcium supplement, 1000 mg	/	//

Phase 2	
erie	
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caler	TIO Phase	7			Completed by Calerie staff: Baseline 1 6 Month Baseline 2 12 Month	srie staff: 6 Months 18 Months 12 Months 24 Months 12 Months 13 Months 14 Months 15 Mont
			Center Number:	: Participant Number:		Participant's Initials: first middle lost
Daily Home Weight Log						
Were you issued a new scale? $\square_0 N_0$ Please complete this log in either blue or		□ 1 Yes → If Yes: Date first used: black ink.	· month day / year	Serial no.:		
Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:
Date:	Date:	Date:	Date:	Date:	Date:	Date:
		` L	i			
lime:	lime:	lime:	Time:	lime:	lime:	Lime:
Weight: 	Weight: lb	Weight: lb	Weight:	Weight:	Weight: 	Weight:
Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:
-		, com	- Control			Date:
Month / day / year	Month day / year	Date: month day / wear —	Month day / year	Date:	Date: month / day / year	month / day / year
Time:	Time: ☐, AM ☐2 PM	Time: ☐, AM ☐ ₂ PM	Time:	Time: 1 AM 2 PM	Time: 1 AM 2 PM	Time: 1 AM 2 PM
		00:00 to 11:59	00:00 to 11:59			
Weight: 	Weight: 	Weight:	Weight:	Weight:	Weight: 	Weight:
						Check scale memory

Send Completed Logs to DCRI Only If Completed During DLW Periods